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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,779	04/08/2005	Elena Ivanovna Dudich	Caspase	2639

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DODDS & ASSOCIATES
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EXAMINER	
HA, JULIE	
ART UNIT	**PAPER NUMBER**
1654	
MAIL DATE	**DELIVERY MODE**
06/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,779	DUDICH ET AL.	
	Examiner	Art Unit	
	Julie Ha	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-8 and 10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *2-8 and 10-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary amendment file on April 08, 2005 is acknowledged. Claims 1 and 9 have been cancelled. Claims 2-8 and 10-21 are pending in this application.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 2-8, 11, 16 and 17, drawn to a linear peptide structure comprising of formula CCR/HGDV/LLD/E_nX_mY, wherein the peptide is polymerized and the first method, a method for increasing preservation of organs or cells within their transplantation.

Group 2, claim(s) 2-8, 16, 17, and 18-21, drawn to a cyclic peptide.

Group 3, claim(s) 11, drawn to a method of use of the cyclic peptide for increasing preservation of organs or cells within their transplantation.

Group 4, claim(s) 12, drawn to a method of use of the linear peptide for prevention of autoimmune disorders and an immunodeficiency syndrome induced by a viral infection.

Group 5, claim(s) 12, drawn to a method of use of the cyclic peptide for prevention of autoimmune disorders and an immunodeficiency syndrome induced by a viral infection.

Group 6, claim(s) 13, drawn to a method of use of the linear peptide for lowering cytotoxic effects after chemo- or radiotherapy.

Group 7, claim(s) 13, drawn to a method of use of the cyclic peptide for lowering cytotoxic effects after chemo- or radiotherapy.

Group 8, claim(s) 14, drawn to a method of use of the linear peptide for inhibition of neuronal cell apoptosis, non-specific drug-induced apoptosis, or oxidative stress-mediated apoptosis.

Group 9, claim(s) 14, drawn to a method use of the cyclic peptide for inhibition of neuronal cell apoptosis, non-specific drug-induced apoptosis, or oxidative stress-mediated apoptosis.

Please note: The "use of" is not a statutory language. The claims reciting "the use of" have been grouped with the Method groupings.

Linking Claims

2. Claims 2, 10 and 15 link(s) inventions 1 and 3 through 9. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 2, 10 and 15. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

3. Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting

rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. A national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) a product and a process specially adapted for the manufacture of said product; or

(2) a product and a process of use of said product; or

(3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) a process and a apparatus specifically designed for carrying out said process; or

(5) a product, a process specially adapted for the manufacture of the said product and an apparatus specifically designed for carrying out said process. 37 CFR 1.475.

Group I, having a first product and a first method for making said product fall within category (2). PCT Rule 13 does not provide for multiple compositions or multiple methods of use within a single application. Thus, the first appearing composition is combined with a corresponding first method of making and the additional composition and method claims each constitute a separate group.

5. The inventions listed as Groups 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The peptide sequences are different and therefore, each sequence is structurally distinct. There is no common structure present, since the claims recite linear or cyclic peptides. The variables recited also give rise to distinct peptides and structures. Search for one would not lead to the other. Additionally, the method groups are patentably independent and distinct because the peptides being used have patentably independent and distinct structures.

6. The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B)

(1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B)

(2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together.

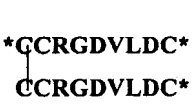
In paragraph (B)(2), above, the words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

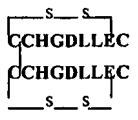
Election

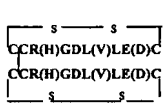
7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Different linear peptides: due to different variables X, Y, n and m;

Different cyclic peptides: 

, 

, or 

;

Different apoptosis: neuronal cell apoptosis, non-specific drug-induced apoptosis, or oxidative stress-mediated apoptosis.

8. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

9. If Group 1or 4 or 6 or 8 is elected, the Applicants are required to elect a single disclosed species of a linear peptide (i.e., a SEQ ID NO or sequence identifier) wherein all of the variables are encompassed by the election to arrive at a single disclosed peptide sequence. Further, if Applicant wants to polymerize, the Applicants are to elect the linear peptide sequence that they want to polymerize (i.e., elect peptide sequence(s) that form the polymer: homopolymers, dimers, etc). If Applicant only elects a liner peptide, then it will be treated as a monomer election, since monomers are different from polymers. If Group 2 or 3 or 5 or 7 or 9 is elected, the Applicants are required to elect a single disclosed species of a cyclic peptide. Further, if Group 8 or 9 is elected, in addition to a single linear or cyclic peptide election, the Applicants are required to elect a single disclosed species of apoptosis.

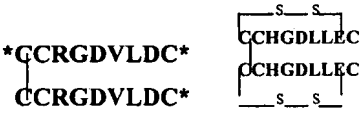
10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

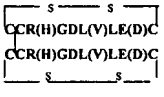
are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. The claims are deemed to correspond to the species listed above in the following manner:

Claims 2, 7 and 14.

The following claim(s) are generic: None.

12. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The linear peptides are patentably independent and distinct because each peptides are structurally different due to different amino acid content. Further, search for one would not lead to the other. Furthermore, the cyclic peptides are patentably independent and distinct because of the different cyclization of the peptide structures. For example, 

, 

and have distinct structures since there are free C-terminal and other functional groups that can have a peptide bond. Apoptosis claimed are patentably independent and distinct due to the target cells and different reasons of apoptosis. Neuronal cell apoptosis targets the neuronal cells, and non-specific drug-induced apoptosis targets other cells, which may not be neuronal cells. Additionally, the causes of the apoptosis are different. Further, search for one would not lead to the other.

13. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

14. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

15. **Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.**

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982. The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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AU 1654

6/21/07
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